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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/227,742 01/08/99 ELI LILLY 042270031US

HM12/0605
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EXAMINER

YUCEL, I

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

06/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/227,742

Applicant(s)

Bloom et al.

Examiner

Remy Yucel

Group Art Unit

1636



☒ Responsive to communication(s) filed on Mar 21, 2000

☒ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 45-71 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 45-71 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1636

DETAILED ACTION

Claims 45-71 are pending in the application. This Office action is in response to the amendment filed 21 March 2000.

Response to Amendment

Claims 45-69 and newly added claims 70 and 71 stand rejected under the judicially created doctrine of obviousness-type double patenting for the reasons set forth in the Office action mailed 22 September 1999.

Claims 45-49 and 51-56 and newly added claims 70 and 71 stand rejected under 35 U.S.C. 102(b) as being anticipated by Inoue *et al.* for the reasons made of record in the Office action mailed 22 September 1999.

Claims 58-69 stand rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative as being unpatentable over de Mendoza *et al.* for the reasons made of record in the Office action mailed 22 September 1999. The basis for this rejection is exactly as set forth in the previous Office action.

The rejection of claims 58-63 and 66 under 35 U.S.C. 102(b) as being anticipated by Emtseva has been withdrawn in light of Applicant's amendments.

The rejection of claims 58-61 and 66-68 under 35 U.S.C. 102(b) as being anticipated by Tsien *et al.* or Kole *et al.* has been withdrawn in light of Applicant's amendments.

The rejection of claims 64-67 under 35 U.S.C. 103(a) as being unpatentable over Emtseva *et al.* in view of either de Mendoza *et al.* or Van Alphen *et al.* has been withdrawn in light of

Art Unit: 1636

Applicant's amendments.

Claims 45-69 and newly added claims 70 and 71 stand rejected under 35 U.S.C. 112, first paragraph for the reasons made of record in the Office action mailed 22 September 1999.

Response to Arguments

With regard to the double patenting rejection, Applicant argues that the instant claims have been amended which has resulted in their being "distinct" from the claims of the '692 patent. This argument has been considered, but not found persuasive because the methods comprise essentially the same method steps, thus it is not clear how the instant claims are distinct from those of the '692 patent. The claims stand rejected.

With regard to the rejection of claims 45-49 and 51-56 and newly added claims 70 and 71 under 35 U.S.C. 102(b) as being anticipated by Inoue *et al.*, Applicant argues that because Inoue *et al.* allegedly fail to teach that their bacteria exhibit both enhanced transformation ability and enhanced viability, the rejection should fall. This argument has been considered, but is not found persuasive for at least two reasons. Applicant is ignoring the *inherent* properties possessed by the bacteria of Inoue *et al.* which would result in not only the disclosed enhanced transformation but increased viability (as corroborated by de Mendoza *et al.*, Ulrich *et al.* and Van Alphen *et al.*). This argument fails to persuade also in light of *In re Spada* 15 USPQ2d 1655(CACF, 1990)-- where it was held that discovery of a new property or use of a previously known composition, even if unobvious from prior art, cannot impart patentability to claims to known composition. The preamble of the claims which extoll the virtues of the resultant bacteria from Applicant's

Art Unit: 1636

methods, does not serve to distinguish said methods from those of the prior art cited. The claims stand rejected.

The same argument is given for the rejection of claims 58-69 as being anticipated by de Mendoza *et al.* Applicant contends that because now the preamble of the claims have been amended to recite enhanced transformation instead of enhance viability, that the de Mendoza *et al.* reference does not apply. This argument has been fully considered in the context of the instant rejection and still remains unpersuasive for the reasons set forth immediately above. In the alternative, the ordinary artisan would have recognized that the benefits of using bacteria having more fluid membranes as a result of an increase of unsaturated fatty acids in said membranes for enhanced viability in transformations. The ordinary artisan would have been motivated to use these bacteria because (1) they were already known in the art to have better viability, thus would be expected to weather the transformation procedures better than bacteria with less fluid membranes (transformation procedures were well known to even the lesser skilled artisans by the time of Applicant's invention) and (2) even intuitively, the ordinary artisan would have expected that more fluid membranes would allow a higher degree of ingress of exogenously added DNA. Thus, the invention would have been obvious over the teachings of de Mendoza *et al.* The claims remain rejected.

In response to the rejection of claims 45-69 and newly added claims 70 and 71 stand rejected under 35 U.S.C. 112, first paragraph, Applicant contends that because references were not provided a *prima facie* case of non-enablement has not been established. Applicant's

Art Unit: 1636

contention that sound scientific reasoning was not presented is completely incorrect. While Applicant may not agree with the reasoning and the detailed analysis of the Forman factors clearly presented in the previous Office action, it is an utter mischaracterization of the rejection of record to alleged that no scientific reasoning was presented in an attempt to negate the rejection of record. Applicant had ample opportunity to indicate those portions of the specification which provides the enablement for the full scope of the claims in each of the sections found at pages 15-20, yet it is noted that not a single portion of the specification was indicated. This completely corroborates the position of the Examiner. Secondly, this issue was similarly dealt with in the parent application, of which the instant application is a continuation. In the absence of new material in the form of a CIP, the instant specification still lacks the teachings necessary to enable the full scope of the claims. Thirdly, with regard to the cited references on page 20 of the remarks, each of the references listed teaches an increase in percentage of unsaturated fatty acids in the membrane--completely corroborating the Examiner's position, indicating that the scope which was originally indicated by the Examiner as being enabled is all that is enabled.

From Applicant's rather circular arguments, it appears that Applicant may not have fully understood the rejection of record. The claimed methods are enabled insofar as they result in an increase in the percentage of unsaturated fatty acids in bacterial membranes. There remains no clear evidence in the specification or in the prior art that a wholesale increase in both saturated and unsaturated fatty acids or saturated fatty acids alone results in increased transformation and viability. Applicant is strongly urged to better define the instant methods as ones in which the

Art Unit: 1636

percentage of unsaturated fatty acids are increased in the bacterial membranes.

Claim Objections

Claim 71 is objected to because of the following informalities: "enchanced" should be --enhanced--. Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR


Art Unit: 1636

§ 1.6 (d)). The Group 1800 FAX numbers are (703) 308-4242 or (703) 305-3014. Unofficial faxes may be sent to the examiner at (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irem Yucel, Ph. D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday through Fridays from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Remy Yucel, Ph. D.
Primary Patent Examiner
AU 1636
June 4, 2000